DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
1401 Rockville Pike
Rockville MD 20852-1448

Our STN: BL 103772/5012

JUN 2 8 2002

Stella S. Jones, Ph.D.
Centocor, Inc.
200 Great Valley Parkway
Malvern, PA 19355

Dear Dr. Jones:

Your request to supplement your biologics license application for Infliximab (Remicade®) to expand the Crohn's disease indication and provide for a maintenance dosing regimen for non-fistulizing disease has been approved. The revised indication is for reducing signs and symptoms, and inducing and maintaining clinical remission in patients with moderately to severely active Crohn's disease who have had an inadequate response to conventional therapy.

We approved your biologics license application for the Crohn's disease indication under the regulations for accelerated approval of biological products for serious or life-threatening illnesses (21 CFR 601 Subpart E). As described in our letter dated August 24, 1998, that approval required you to complete certain specified studies. We acknowledge that you have fulfilled part of your commitment made under 21 CFR 601.41 to complete a randomized, double-blind, placebo-controlled clinical study(s) to evaluate safety and efficacy of continued use of Infliximab for maintaining a sustained clinical outcome in patients with moderately to severely active Crohn's disease. However, we have not received results of your study in patients with draining enterocutaneous fistula(s); thus, that commitment remains outstanding.

Please submit all final printed labeling at the time of use and include implementation information on FDA Form 2567. Please provide a PDF-format electronic copy as well as original paper copies (ten for circulars and five for other labels). In addition, you may wish to submit draft copies of the proposed introductory advertising and promotional labeling with an FDA Form 2567 or Form 2253 to the Center for Biologics Evaluation and Research, Advertising and Promotional Labeling Branch, HFM-602, 1401 Rockville Pike, Rockville, MD 20852-1448. Final printed advertising and promotional labeling should be submitted at the time of initial dissemination, accompanied by an FDA Form 2567 or Form 2253.

All promotional claims must be consistent with and not contrary to approved labeling. No comparative promotional claim or claim of superiority over other products should be made

unless data to support such claims are submitted to and approved by the Center for Biologics Evaluation and Research.

This information will be included in your biologics license application file.

Sincerely yours,

Patricia Keegan for Dr. Weiss

Karen D. Weiss, M.D.
Director
Division of Clinical Trial
Design and Analysis
Office of Therapeutics
Research and Review
Center for Biologics
Evaluation and Research